From: Hebert, John
To: Dunn, Meghan

Subject: Re: Accepted Label for Reg. No. 7173-174; time-sensitive question

Date: Friday, February 01, 2013 11:50:11 AM

Hi Meghan - Sorry, I didn't proof the label before I sent it to you. (Be careful....I might start sending other labels for you to review!). I think I'm OK with the container label mainly because this is a technical. I think the Note to Physician adequately captures everything that it needs to. And because it's only used for manufacturing other rodenticides the dog language is overkill and really doesn't need to be there. Let me know if you have other questions. Have a great weekend....

john

John Hebert, PM7

Insecticide-Rodenticide Branch

Registration Division

Office of Pesticide Programs

703-308-6249

From: Meghan Dunn/R5/USEPA/US

To: John Hebert/DC/USEPA/US@EPA

Date: 01/31/2013 01:59 PM

Subject: Re: Accepted Label for Reg. No. 7173-174; time-sensitive question

Hi John,

Thanks for the updated label, and your fast response. The 9/28/08 label does match the label provided with the import Notice of Arrival much more nicely.

I did notice that the physician/veterinarian notes are still different on the two versions.

The import label version states:

Note to physician: If swallowed or absorbed through the skin, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K1 intramuscularly or orally. Repeat as necessary based on monitoring of prothrombin times. In severe cases, blood transfusions may be necessary. Treatment for Pet Poisoning: If animal eats bait, call veterinarian at once. Note to Veterinarian: Anticoagulant bromadiolone: For animals ingesting bait and/or showing poison signs (bleeding or prolonged prothrombin times), give Vitamin K1. If needed, check prothrombin times every 3 days until values return to normal (up to 30 days). In severe cases, blood transfusions may be necessary.

The 9/28/08 accepted label states:

Note to physician or veterinarian: Contains bromadiolone, an anticoagulant. For humans or dogs that have ingested this product, or have obvious poisoning symptoms (bleeding) or elevated prothombin times, give Vitamin K1 by intramuscular or oral administration. In severe cases, blood transfusions may be necessary. Check prothrombin time every 3 days until values return to normal.

Is the import label version acceptable?
Thanks
Meghan
Meghan Dunn
Environmental Scientist
Pesticides and Toxics Compliance Section
U.S. EPA, Region 5
(312) 886-6191
From: John Hebert/DC/USEPA/US
To: Meghan Dunn/R5/USEPA/US@EPA,
Date: 01/31/2013 12:29 PM
Subject: Re: Accepted Label for Reg. No. 7173-174; time-sensitive question
Hi Meghan - There was a more recent label (attached) that was accepted Sept 29, 2008. This is the reregistration label that includes all the mitigation language from the Rodenticide Mitigation Decision. I don't know why this label is not in PPLS - sorry about that. Let me know if you have any questions.
Regards,
John
[attachment "[Untitled].pdf" deleted by Meghan Dunn/R5/USEPA/US]
John Hebert, PM7
Insecticide-Rodenticide Branch
Registration Division

Office of Pesticide Programs

703-308-6249

From: Meghan Dunn/R5/USEPA/US

To: John Hebert/DC/USEPA/US@EPA

Date: 01/31/2013 10:34 AM

Subject: Accepted Label for Reg. No. 7173-174; time-sensitive question

John,

Maybe you remember me, I'm a FIFRA enforcement officer in R5 and Claudia Niess and I called you with a few questions not too long ago.

I have some new questions - I'm reviewing a Notice of Arrival for a product, Maki Technical (Reg. No. 7173-174), imported by Liphatech. The label appears to differ from the most recent accepted label in OPPIN, which is from 8/1/05,

Is there a more recent accepted label than the 8/1/05 one? If not, are the changes are acceptable? I've attached the label provided with the Notice of Arrival.

Changes were made primarily in the Note to Physician/Veterinarian sections of the First Aid section, the Directions for Use, and Storage and Disposal. I won't spell out the changes here in the interest of saving time in case there is a newer accepted label. Generally the attached label shows an addition of more detailed statements in each of these sections compared to the accepted label.

Thanks,

Meghan

[attachment "Maki Technical current label.pdf" deleted by John Hebert/DC/USEPA/US]

Meghan Dunn

Environmental Scientist

Pesticides and Toxics Compliance Section

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